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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R.

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. WENSTRUP introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Step Act”.

1 **SEC. 2. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**
2 **TION STEP THERAPY PROTOCOLS.**

3 (a) IN GENERAL.—The Employee Retirement Income
4 Security Act of 1974 is amended by inserting after section
5 725 of such Act (29 U.S.C. 1185d) the following new sec-
6 tion:

7 **“SEC. 726. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**
8 **TION STEP THERAPY PROTOCOLS.**

9 “(a) IN GENERAL.—In the case of a group health
10 plan or health insurance coverage offered in connection
11 with such a plan that provides coverage of a prescription
12 drug pursuant to a medication step therapy protocol, the
13 plan or coverage shall—

14 “(1) implement a clear and transparent process
15 for a participant or beneficiary (or the prescribing
16 health care provider on behalf of the participant or
17 beneficiary) to request an exception to such medica-
18 tion step therapy protocol, pursuant to subsection
19 (b); and

20 “(2) where the participant or beneficiary or
21 prescribing health care provider’s request for an ex-
22 ception to the medication step therapy protocols sat-
23 isfies the criteria and requirements of subsection (b),
24 cover the requested drug in accordance with the
25 terms established by the health plan or coverage for
26 patient cost-sharing rates or amounts at the time of

1 the participant's or beneficiary's enrollment in the
2 health plan or health insurance coverage.

3 “(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—

4 The circumstances requiring an exception to a medication
5 step therapy protocol, pursuant to a request under sub-
6 section (a), are any of the following:

7 “(1) Any treatments otherwise required under
8 the protocol, or treatments in the same pharma-
9 cological class or having the same mechanism of ac-
10 tion, have been ineffective in the treatment of the
11 disease or condition of the participant or beneficiary,
12 when prescribed consistent with clinical indications,
13 clinical guidelines, or other peer-reviewed evidence.

14 “(2) Delay of effective treatment would lead to
15 severe or irreversible consequences, and the treat-
16 ment otherwise required under the protocol is rea-
17 sonably expected to be ineffective based upon the
18 documented physical or mental characteristics of the
19 participant or beneficiary and the known character-
20 istics of such treatment.

21 “(3) Any treatments otherwise required under
22 the protocol are contraindicated for the participant
23 or beneficiary or have caused, or are likely to cause,
24 based on clinical, peer-reviewed evidence, an adverse

1 reaction or other physical harm to the participant or
2 beneficiary.

3 “(4) Any treatment otherwise required under
4 the protocol has prevented, will prevent, or is likely
5 to prevent a participant or beneficiary from achiev-
6 ing or maintaining reasonable and safe functional
7 ability in performing occupational responsibilities or
8 activities of daily living (as defined in section
9 441.505 of title 42, Code of Federal Regulations (or
10 successor regulations)).

11 “(5) The participant or beneficiary is stable for
12 his or her disease or condition on the prescription
13 drug or drugs selected by the prescribing health care
14 provider and has previously received approval for
15 coverage of the relevant drug or drugs for the dis-
16 ease or condition by any group health plan or health
17 insurance issuer.

18 “(6) Other circumstances, as determined by the
19 Secretary.

20 “(c) REQUIREMENT OF A CLEAR PROCESS.—

21 “(1) IN GENERAL.—The process required by
22 subsection (a)—

23 “(A) shall provide the prescribing health
24 care provider or beneficiary or designated third-
25 party advocate an opportunity to present such

1 provider's clinical rationale and relevant med-
2 ical information for the group health plan or
3 health insurance issuer to evaluate such request
4 for exception;

5 “(B) shall clearly set forth all required in-
6 formation and the specific criteria that will be
7 used to determine whether an exception is war-
8 ranted, which may require disclosure of—

9 “(i) the medical history or other
10 health records of the participant or bene-
11 ficiary demonstrating that the participant
12 or beneficiary seeking an exception—

13 “(I) has tried other drugs in-
14 cluded in the drug therapy class with-
15 out success; or

16 “(II) has taken the requested
17 drug for a clinically appropriate
18 amount of time to establish stability,
19 in relation to the condition being
20 treated and prescription guidelines
21 given by the prescribing physician; or

22 “(ii) other clinical information that
23 may be relevant to conducting the excep-
24 tion review;

1 “(C) may not require the submission of
2 any information or supporting documentation
3 beyond what is strictly necessary to determine
4 whether any of the circumstances listed in sub-
5 section (b) exists; and

6 “(D) shall clearly outline conditions under
7 which an exception request warrants expedited
8 resolution from the group health plan or health
9 insurance issuer, pursuant to subsection (d)(2).

10 “(2) AVAILABILITY OF PROCESS INFORMA-
11 TION.—The group health plan or health insurance
12 issuer shall make information regarding the process
13 required under subsection (a) readily available on
14 the internet website of the group health plan or
15 health insurance issuer. Such information shall in-
16 clude—

17 “(A) the requirements for requesting an
18 exception to a medication step therapy protocol
19 pursuant to this section; and

20 “(B) any forms, supporting information,
21 and contact information, as appropriate.

22 “(d) TIMING FOR DETERMINATION OF EXCEP-
23 TION.—The process required under subsection (a)(1) shall
24 provide for the disposition of requests received under such
25 paragraph in accordance with the following:

1 “(1) Subject to paragraph (2), not later than
2 72 hours after receiving an initial exception request,
3 the plan or issuer shall respond to the requesting
4 prescriber with either a determination of exception
5 eligibility or a request for additional required infor-
6 mation strictly necessary to make a determination of
7 whether the conditions specified in subsection (b)
8 are met. The plan or issuer shall respond to the re-
9 questing provider with a determination of exception
10 eligibility no later than 72 hours after receipt of the
11 additional required information.

12 “(2) In the case of a request under circum-
13 stances in which the applicable medication step ther-
14 apy protocol may seriously jeopardize the life or
15 health of the participant or beneficiary, the plan or
16 issuer shall conduct a review of the request and re-
17 spond to the requesting prescriber with either a de-
18 termination of exception eligibility or a request for
19 additional required information strictly necessary to
20 make a determination of whether the conditions
21 specified in subsection (b) are met, in accordance
22 with the following:

23 “(A) If the plan or issuer can make a de-
24 termination of exception eligibility without addi-
25 tional information, such determination shall be

1 made on an expedited basis, and no later than
2 24 hours after receipt of such request.

3 “(B) If the plan or issuer requires addi-
4 tional information before making a determina-
5 tion of exception eligibility, the plan or issuer
6 shall respond to the requesting provider with a
7 request for such information within 24 hours of
8 the request for a determination, and shall re-
9 spond with a determination of exception eligi-
10 bility as quickly as the condition or disease re-
11 quires, and no later than 24 hours after receipt
12 of the additional required information.

13 “(e) MEDICATION STEP THERAPY PROTOCOL.—In
14 this section, the term ‘medication step therapy protocol’
15 means a drug therapy utilization management protocol or
16 program under which a group health plan or health insur-
17 ance issuer offering group health insurance coverage of
18 prescription drugs requires a participant or beneficiary to
19 try an alternative preferred, prescription drug or drugs be-
20 fore the plan or health insurance issuer approves coverage
21 for the non-preferred drug therapy prescribed.

22 “(f) CLARIFICATION.—This section shall apply with
23 respect to any group health plan or health insurance cov-
24 erage offered in connection with such a plan that provides
25 coverage of a prescription drug pursuant to a policy that

1 meets the definition of the term ‘medication step therapy
2 protocol’ in subsection (e), regardless of whether such pol-
3 icy is described by such group health plan or health insur-
4 ance coverage as a step therapy protocol.”.

5 (b) CLERICAL AMENDMENT.—The table of contents
6 in section 1 of the Employee Retirement Income Security
7 Act of 1974 (29 U.S.C. 1001 et seq.) is amended by in-
8 serting after the item relating to section 725 the following
9 new items:

“Sec. 726. Required exceptions process for medication step therapy protocols.”.

10 (c) EFFECTIVE DATE.—

11 (1) IN GENERAL.—The amendment made by
12 subsection (a) applies with respect to plan years be-
13 ginning with the first plan year that begins at least
14 6 months after the date of the enactment of this
15 Act.

16 (2) REGULATIONS.—Not later than 6 months
17 after the date of the enactment of this Act, the Sec-
18 retary of Labor shall issue final regulations, through
19 notice and comment rulemaking, to implement the
20 provisions of section 726 of the Employee Retire-
21 ment Income Security Act of 1974, as added by sub-
22 section (a).